REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

Status of the Claims

Pending claims

Claims 1, 2, 6, 11, 12, 16, 29, 47 to 62, 68 to 75, 87, 88, 95 to 107, 111 to 115, 117 to 122 and 130 to 132 are pending. Claims 49 to 73, 95 to 100, 107, 111 to 115 and 117 to 122 are withdrawn from consideration. Accordingly, claims 1, 2, 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132 are pending and under consideration.

Claims added in the instant amendment

In the present response, claims 133 to 152 are added. Thus, after entry of the instant amendment, claims 1, 2, 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 152 will be pending and under consideration.

Outstanding Rejections

Claims 47, 48, 130 and 132 are rejected under 35 U.S.C. §101. Claims 1, 2, 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132, stand rejected under 35 U.S.C. §112, second paragraph. Claims 2, 74 to 88, 101 to 106 and 130 to 132 stand rejected under 35 U.S.C. §112, first paragraph, written description requirement. Claims 1, 2, 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132, stand rejected under 35 U.S.C. §112, first paragraph, enablement requirement. Claims 1, 2 and 74 (and because they are dependent, claims 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132) are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Imanaka, et al., GenBank Accession No. E13334, 4-28-1998 ("Imanaka").

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the claim Amendments

The specification sets forth an extensive description of the invention as set forth in the pending, new and amended claims. For example, support for claims directed to various hybridization conditions, including various wash step conditions can be found, inter alia, in paragraph [0165], page 48, of the specification as filed (which is paragraph [0183] of this application's publication U.S. Pat. App. No. 20030170634, "the '634 publication"); and paragraph [0190] of the '634 publication. Support for very highly stringent hybridization conditions can be found, inter alia, in paragraph [0172], pages 49, 50 of the application as filed (which is paragraph [0190] of the '634 publication). Support for nucleic acid that specifically hybridize under highly stringent hybridization conditions, e.g., 0.1x SSC, 0.5% SDS for 15 to 30 minutes at between the hybridization temperature and 68 degrees C (high stringency); and 0.15M NaCl for 15 minutes at 72 degrees C. (very high stringency) can be found, inter alia, in paragraph [0190] of the '634 publication. Support for methods that use nucleic acids of the invention (to made enzymes of the invention), including corn wet milling processes, processes to liquefy starch, and processes that produce corn oil, gluten meal, gluten feed and/or starch, can be found, inter alia, in paragraphs [0047] and [0076] of the '634 publication. Support for methods that use nucleic acids of the invention (to made enzymes of the invention) for drilling processes can be found, inter alia, in paragraph [0081] of the '634 publication. Support for methods that use nucleic acids of the invention (to made enzymes of the invention), including liquefaction of starch processing; in wet corn milling; in alcohol production; as cleaning agents in detergent matrices; in the textile industry for starch desizing; in baking applications; in the beverage industry; in oilfields in drilling processes; in inking of recycled paper; in animal feed; in textile desizing, brewing processes; starch modification in the paper and pulp industry; and other processes described in the art can be found, inter alia, in paragraphs [0003], [0032], [0077] to [0079] of the '634 publication.

The Restriction Requirement, Election and Traversal

The Patent Office alleged that the pending claims of the application are directed to nineteen (XIX) separate and distinct inventions under 35 U.S.C. §121. In response, Applicants elected Group I, claims 1 to 29, 47, 48, 74 to 92 and 101 to 106, drawn to polynucleotides, vectors, host cells comprising same, probes for same and a method of making a polypeptide using the

polynucleotides of the invention, with traverse, giving reasons to reconsider and withdraw the restriction requirement.

Rejoining claims under In re Ochiai

Applicants respectfully request that after the elected product claims have been found to be allowable all withdrawn process (methods) claims which depend from or otherwise include all of the limitations of the allowed product claims be rejoined. MPEP §821.04; pg 800-63 to 800-70, 8th Ed., Rev. 3, Aug. 2005; In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995); In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1995); 1184 OG 86, 3/26/96.

Applicants respectfully request that after the elected product claims have been found to be allowable, the withdrawn process (methods) claims of Groups IV, VII, VIII, IX, XI, XIII, XIV, XV, XVI, XVIII and XIX should be rejoined.

Issues under 35 U.S.C. §101

Claims 47, 48, 130 and 132 are rejected under 35 U.S.C. §101, as allegedly drawn to non-statutory subject matter, for reasons set forth on pages 2 to 3, of the OA. The instant amendment addresses these issues.

Issues under 35 U.S.C. §112, second paragraph

Claims 1, 2, 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132, stand rejected under 35 U.S.C. §112, second paragraph, for reasons set forth on pages 3 to 4 of the OA. The instant amendment addresses these issues.

Accordingly, the rejection under section 112, second paragraph, can be properly withdrawn.

Issues under 35 U.S.C. §112, first paragraph

Written Description

Claims 2, 74 to 88, 101 to 106 and 130 to 132 stand rejected under 35 U.S.C. §112, first paragraph, written description requirement, for reasons set forth on pages 4 to 5, of the OA. The instant amendment addresses these issues.

Regarding support for nucleic acid that specifically hybridize under highly stringent hybridization conditions, e.g., 0.1x SSC, 0.5% SDS for 15 to 30 minutes at between the

hybridization temperature and 68 degrees C (high stringency); and 0.15M NaCl for 15 minutes at 72 degrees C. (very high stringency) can be found in paragraph [0190] of the '634 publication.

Accordingly, the written description rejection under section 112, first paragraph, can be properly withdrawn.

Enablement

Claims 1, 2, 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132 stand rejected under 35 U.S.C. §112, first paragraph, enablement requirement, as allegedly not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention, for reasons set forth on pages 5 to 8, of the OA.

The Office does note that the specification is enabling for, inter alia, a polynucleotide that is at least 95% identical to SEQ ID NO:1 encoding a polypeptide having amylase activity.

Fully complementary sequences

However, the Office remains concerned that sequences that are only partially complementary to the claimed genus of nucleic acids (polynucleotides that are at least 95% identical to SEQ ID NO:1) are within the scope of the claim. The instant amendment addresses these issues.

Probes

The Office also remains concerned that the claimed genus of nucleic acid probes is too broad, thus requiring undue experimentation to make and use them, because inter alia the defining function of the probes' nucleic acid sequences is to identify amylase-encoding sequences by hybridizing to them under defined highly stringent conditions, while these sequences do not themselves encode an amylase (as correctly noted by the Office, see, e.g., page 7, lines 11 to 12, of the OA).

To address the scope, or breadth, of the claimed genus of nucleic acid probes, claim 74 is amended to be expressly limited in scope to only encompass nucleic acids having at least 90% sequence identity to SEQ ID NO:1 or its fully complementary sequence (see discussion below regarding section 102 issues).

The Office implies that a biological function must be attached to a sequence of sequences to help satisfy section 112, first paragraph (see, e.g., page 8, lines 5 to 7, of the OA). While Applicants

acknowledge that all species members of a genus of biological sequences must have a structure-function relationship, they respectfully aver that the linking functional limitation of the members of the genus does not necessary have to be its natural biological function, but can be another function, e.g., as a research tool, for example, a probe to isolate or identify a protein-encoding sequence.

Accordingly, one of skill in the art using the specification as guidance would not have to apply undue experimentation to make and use the claimed genus of probes (for identifying and/or isolated amylase-encoding nucleic acids).

Because Applicants' previous responses are expressly incorporated herein, they will not be reiterated in this submission. However, because one of the Office's concerns is that it would have taken undue experimentation to make the genus of probes used to practice this invention, Applicants believe a brief review of the standard used in determining undue experimentation as set forth in In re Wands would be helpful:

Applicants have maintained that the specification provided reasonable enablement regarding the structure and sequence of the genera of claimed nucleic acid probes. Whether large numbers of compositions (e.g., a genus of probes for identifying or isolating amylase-encoding nucleic acids) must be screened to determine if one can be used to practice the claimed invention is irrelevant to an enablement inquiry. Enablement is not precluded by the necessity to screen large numbers of compositions, as long as that screening is "routine," i.e., not "undue," to use the words of the Federal Circuit. The Federal Circuit in In re Wands directed that the focus of the enablement inquiry should be whether the experimentation needed to practice the invention is or is not "undue" experimentation. Guidance as to how much experimentation may be needed and still not be "undue" was set forth by the Federal Circuit in, e.g. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987), which was discussed in Applicants' response of July 17, 2003.

The proper legal test is that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). See MPEP §2164.08, pg 2100-205, 206, 8th ed., rev. 3, Aug. 2005. `The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to

the direction in which the experimentation should proceed.' " In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). MPEP §2164.06(b), pg 2100-203, 8th ed., rev. 3, Aug. 2005.

The facts in In re Wands are sufficiently analogous to the instant application to help illustrate this point, as explained in the MPEP (§2164.06(b), pg 2100-203, 8th ed., rev. 3, Aug. 2005):

> (B) In In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under 35 U.S.C. 112, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with the desired characteristics. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

In In re Wands, after considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." Id., 8 USPQ2d at 1407. In In re Wands, it was not necessary to provide a method to routinely identify *every* monoclonal antibody hybridoma made in any particular production round, or *every possible* monoclonal antibody that could bind the exemplary antigen. Nor was it necessary to produce a working specie after very antibody-making procedure. In fact, in In re Wands, the screening protocol was found sufficiently enabling even though only one antibody was identified after running three procedures.

Analogous to In re Wands, it is not necessary that the specification or the state of the art at the time of the invention describe a protocol where every, or even most, attempts at making a probe (within the limitations of the claimed invention) are successful. Because proper legal test is that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims, as in In re Wands, methods for making the claimed genera of probes for identifying or isolating amylase-

encoding nucleic acids are sufficiently enabling if a reasonable number of species are successfully made by protocols known in the art and/or described in the specification. Protocols for making nucleic acids that can hybridize to an exemplary nucleic acid sequence under defined stringent hybridization conditions were well known in the art at the time of the invention; see e.g., paragraphs [0175] to [0195] of the '634 publication.

Thus, using the teaching of the specification and other protocols known in the art at the time of the invention one skilled in the art could have successfully practiced the invention without undue experimentation, including making and using the claimed genera of probes for identifying or isolating amylase-encoding nucleic acids without undue experimentation. In other words, methods for making and screening for probes that can specifically bind to an exemplary sequence under defined stringent hybridization conditions were sufficiently sophisticated and well known at the time of the invention that one of skill in the art could have made the genus of claimed probes without "undue experimentation", according to the appropriate legal definition of this term, e.g., as in In re Wands.

Furthermore, also analogous to In re Wands, because the specification provided direction and guidance on how to practice the claimed invention and all of the methods needed to practice the invention were well known, and there was a high level of skill in the art at the time the application was filed, the instant specification did provide reasonable enablement commensurate with the scope of the claimed invention. Accordingly, the enablement rejection under section 112, first paragraph, can be properly withdrawn.

In light of the above remarks and the present claim amendments, Applicants respectfully submit that amended claims are fully enabled by and described in the specification to overcome the rejection based upon 35 U.S.C. §112, first paragraph.

Issues under 35 U.S.C. §102(b)

Claims 1, 2 and 74 (and because they are dependent, claims 6, 12, 16, 29, 47, 48, 74, 75, 87, 88, 101 to 106 and 130 to 132) are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Imanaka, et al., GenBank Accession No. E13334, 4-28-1998 ("Imanaka").

The instant amendment addresses this issue; e.g., claims 1 and 2 are now encompass, inter alia, only fully complementary sequences.

Applicants note that their analysis of the sequence disclosed by Imanaka has it only 85% sequence identity to the full length of the exemplary SEQ ID NO:1. Thus, to address the Office's concerns regarding Imanaka, claim 74 is amended to expressly encompass only sequences that have at least 90% sequence identity to SEQ ID NO:1. Thus, after entry of the instant amendment, the probe sequences of the invention expressly do not read on the sequence disclosed by Imanaka.

In light of the above remarks and the present claim amendments, Applicants respectfully submit that the rejection based upon 35 U.S.C. §102 can be properly withdrawn.

CONCLUSION

Applicants respectfully submit that after entry of the instant amendment all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Applicants believe that no fees are necessitated by the present response and amendment. However, in the event any such fees are due, the Commissioner is hereby authorized to charge any such fees to **Deposit Account No. 03-1952** referencing attorney Docket No. **564462006000**. Please credit any overpayment to this account.

If another telephonic conference would expedite prosecution of this application, please telephone the undersigned at 858-720-5133.

Dated: August 2, 2006

Respectfully submitted,

By _____
Gregory P. Einhorn
Registration No.: 38,440
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego CA 92130-2040
direct dial 858 720 5133
general office 858 720 5100
fax direct 858 523 5933
fax office 858 720 5125